



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-N-2312]

Request for Nominations From Industry Organizations Interested in Participating in the Selection Process for Nonvoting Industry Representatives and Request for Nominations for Nonvoting Industry Representatives on the Allergenic Products Advisory Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is requesting that any industry organizations interested in participating in the selection of a nonvoting industry representative to serve on the Allergenic Products Advisory Committee (APAC) for the Center for Biologics Evaluation and Research notify FDA in writing. FDA is also requesting nominations for a nonvoting industry representative(s) to serve on the APAC. A nominee may either be self-nominated or nominated by an organization to serve as a nonvoting industry representative. Nominations will be accepted for current vacancies effective with this notice.

DATES: Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interests must send a letter stating that interest to FDA by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*], (see sections I and II of this document for further details). Concurrently, nomination materials for prospective candidates should be sent to FDA by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: All statements of interest from industry organizations interested in participating in the selection process of nonvoting industry representative nominations should be sent to Serina Hunter-Thomas (see FOR FURTHER INFORMATION CONTACT). All nominations for nonvoting industry representatives may be submitted electronically by accessing the FDA Advisory Committee Membership Nomination Portal:

<https://www.accessdata.fda.gov/scripts/FACTRSPortal/FACTRS/index.cfm>. Information about becoming a member of an FDA advisory committee can also be obtained by visiting FDA's website at: <http://www.fda.gov/AdvisoryCommittees/default.htm>.

FOR FURTHER INFORMATION CONTACT: Serina Hunter-Thomas, Division of Scientific Advisors and Consultants, Center for Biologics Evaluation and Research, 10903 New Hampshire Ave., Bldg. 71, Rm. 6338, Silver Spring, MD 20993-0002, 240-402-5771, Fax: 301-595-1307, email: Serina.Hunter-Thomas@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: The Agency intends to add a nonvoting industry representative(s) to the following advisory committee:

I. Allergenic Products Advisory Committee

The committee reviews and evaluates data concerning the safety, effectiveness, and adequacy of labeling of marketed and investigational allergenic biological products or materials that are administered to humans for the diagnosis, prevention, or treatment of allergies and allergic disease, and makes appropriate recommendations to the Commissioner of Food and Drugs (the Commissioner) of its findings regarding the affirmation or revocation of biological product licenses; on the safety, effectiveness, and labeling of the products; on clinical and laboratory studies of such products; on amendments or revisions to regulations governing the manufacture, testing, and licensing of allergenic biological products; and on the quality and

relevance of FDA's research programs which provide the scientific support for regulating these agents.

II. Selection Procedure

Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interests should send a letter stating that interest to the FDA contact (see FOR FURTHER INFORMATION CONTACT) within 30 days of publication of this document (see DATES). Within the subsequent 30 days, FDA will send a letter to each organization that has expressed an interest, attaching a complete list of all such organizations; and a list of all nominees along with their current resumes. The letter will also state that it is the responsibility of the interested organizations to confer with one another and to select a candidate, within 60 days after the receipt of the FDA letter, to serve as the nonvoting member to represent industry interests for the committee. The interested organizations are not bound by the list of nominees in selecting a candidate. However, if no individual is selected within 60 days, the Commissioner will select the nonvoting member to represent industry interests.

III. Application Procedure

Individuals may self-nominate and/or an organization may nominate one or more individuals to serve as a nonvoting industry representative. Contact information, a current curriculum vitae, and the name of the committee of interest should be sent to the FDA Advisory Committee Membership Nomination Portal (see ADDRESSES) within 30 days of publication of this document (see DATES). FDA will forward all nominations to the organizations expressing interest in participating in the selection process for the committee. (Persons who nominate themselves as nonvoting industry representatives will not participate in the selection process).

FDA seeks to include the views of women and men, members of all racial and ethnic groups, and individuals with and without disabilities on its advisory committees and, therefore, encourages nominations of appropriately qualified candidates from these groups.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: June 11, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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